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10/057,202

01/23/2002

M. Reza Movahed

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07/02/2004

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/057,202

Applicant(s)

MOVAHED, M. REZA

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5-22,24-36,39-43,46,47,49-53 and 55-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-22,24-36,39-43,51-53 and 67-95 is/are allowed.
- 6) ☒ Claim(s) 3,6-16,46,47,49,50 and 55-66 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 06242004.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The indicated allowability of claim 4 is withdrawn in view of the newly discovered reference(s) to St. Goar et al. Rejections based on the newly cited reference(s) follow.

### ***Specification***

2. The disclosure is objected to because of the following informalities: On page 12 line 14, it appears that "3" should be changed to --30--. Appropriate correction is required.

### ***Claim Objections***

3. Claim 51 is objected to because of the following informalities: In claim 51 line 12, it appears that "herein" should be changed to --wherein--.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6-14, 46, 47, 49, 50 and 55-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of claims 6-14 cannot be clearly ascertained because it appears that the suction device comprising a pump as set forth by claims 6-14 conflicts with amended parent claim 3 which limits the suction device to a syringe. Furthermore, there appears to be no support in the specification for the suction device comprising both embodiments simultaneously (see

p. 21 lines 4-8). In claim 46, the scope cannot be reasonably ascertained because it is unclear whether the "injected substance" is the same as "said contrast" in lines 9-10. It appears that "an injected substance" in lines 1-2 and "injected substance" in line 5 should be changed to –contrast—so as to be consistent with "said contrast," and the visual means for determining the presence of the contrast, in lines 9 and 10. In claim 55, the scope cannot be clearly ascertained since it is not explicit whether the suction device in line 6 encompasses a pump or syringe. It appears that –comprising a pump-- should be inserted after "suction device" in line 6 for clarification and to be consistent with "said pump" in lines 9-10 and 11.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3, 6, 8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich of record in view of St. Goar et al.

[The examiner notes that, apart from the visualization means, the apparatus of the present invention is not structurally specific to the introduction and removal of contrast fluids in that it may also be used for introduction and removal of therapeutic/medication fluids (see page 4 of the specification lines 19-22)].

Regarding claims 3 and 6, Reich teaches all of the claimed subject matter except that the venting catheter having a suction device in the form of a syringe or pump is not

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addressed explicitly. Reich however does teach that the drainage flow rate may be somehow controlled to allow corrective action to be taken when sensed pressure in the heart is too high or low (col. 3 lines 25-30). St. Goar et al. generally teach that it is known that coronary venting catheters may be vented by gravity or by application of negative pressure with a syringe or pump (col. 6 lines 38-41, col. 16 lines 19-25) (capable of starting and stopping at specific times) and that retrograde perfusion catheters may be used as venting catheters (col. 16 lines 39-51). Akin to Reich, St. Goar et al. also discloses distal pressure sensors. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to vent the heart by means of a syringe or pump as taught by St. Goar et al. in the invention as taught by Reich since such means are well known and provide fast and/or direct control of fluid pressure in the heart and veins. Regarding claim 8, although St. Goar et al. does not explicitly disclose automatically turning the pump on or off, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to automatically turn the pump off as soon as it is sensed that the distal pressure is too low to avoid injury to the patient as quickly as possible.

Regarding claims 15 and 16, Reich differs from the claimed invention in that shaped catheters are not specifically addressed. St. Goar et al. generally teaches that pre-shaped selective curves for different anatomies are well known in the art for angiographic procedures as well as guidewire placement (col. 5 lines 8-12). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a shaped or steerable catheter as taught by St. Goar et al. in the invention

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as taught by Reich to provide easier and less traumatic access to the heart as is well known in the art. Additionally, lacking any criticality, the specific shape used to introduce the catheter through the femoral vein would have been an obvious matter of design choice to a person of ordinary skill in the art without undue experimentation.

***Allowable Subject Matter***

6. Claims 17-22, 24-36, 39-43, 51-53, 67-95 are allowed. Regarding claims 17, 36, 51, 67, 85, the prior art does not fairly teach or suggest a method for angiographically/radiographically monitoring and controllably removing an injected substance in blood upstream from an occlusion as set forth by the present invention.

7. Claim 46 and 55 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Regarding claims 46 and 55, the prior art does not fairly teach or suggest an apparatus for removing injected contrast from a vessel upstream from an occlusion including visual means for monitoring the contrast as set forth by the present invention.

8. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 7, 9-14, 47, 49, 50 and 55-66 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

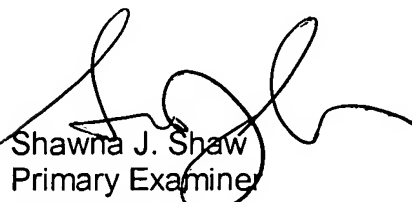
**Conclusion**

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilder et al. (3,841,331) demonstrates that suction by means of syringes and pumps is old and well established.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw  
Primary Examiner  
6/24/2004